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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,862	09/13/2000	William Pollack	ATOPH:52516	7947

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	18

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/660,862	POLLACK, WILLIAM	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *14* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This Office Action is responsive to Applicant's amendment and response filed August 7, 2002. Claims 6 and 7 have been amended. Claims 1 and 5-9 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment the following rejections have been withdrawn:

a) Rejection of claim 1 under 35 U.S.C. 112, second paragraph, pages 3-4, paragraph 6 of previous Office action.
b) Rejection of claim 1 under U.S.C. 102(b), pages 4-5, paragraph 7, of the previous Office action.
c) Rejection of claims 1 and 5-9 under 35 U.S.C. 103(a), pages 5-8, paragraph 8 of the previous Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 and 5-9 are rejected under 35 U.S.C. 35 U.S.C. 103(a) as being unpatentable over Laursen et al *(US Patent No. 6,281,336, published August 23, 2001)* in view of Flaa et al *(U.S. Patent No. 6,165,981 published December 26, 2000).*

Laursen et al teach a method of producing immunoglobulins and other immunoglobulin products (see the Title). Laursen et al teach a method of producing IgG4 (see Example 2, columns 17-18 and column 20, lines 9-15). Laursen et al teach the use of DEAE Sepharose® and CM-Sepharose® exchange resins in the method of producing immunoglobulin and immunoglobulin products (column 7). Laursen et al teach a method of producing immunoglobulins by starting with normal human plasma or plasma from donor with high titers of specific antibodies (i.e. hyperimmune plasma) (column 4). Laursen et al teach that the method for producing IgG immunoglobulins and immunoglobulin products include: 1) purification of the Cohn fraction by preparing Cohn fraction from human plasma by adjusting the pH, ethanol concentration, adjusting temperature and protein concentration, 2) extraction of the immunoglobulin from the Cohn extraction by adding sodium phosphate, adjusting pH, filtering, centrifuging and re-filtering the suspension and 3) purification of by serial anion and cation exchange chromatography using DEAE Sepharose® and CM-Sepharose® resins. Laursen et al teach that the IgG is eluted with a gradient of NaCl when the CM-Sepharose column is used (column 15-16). Laursen et al teach the addition of saccharides to the IgG fraction to stabilize and adjust the osmolality of the IgG fraction (column 9, lines 17-26 and column 4, lines 20-23). Laursen et al teach an osmolality of 347-350 mOsm/kg (column 23) and a pH range of 4.0-6.0 for the IgG immunoglobulin fraction (column 5, lines 12-

14). Laursen et al teach that the products obtained from the invention can be freeze-dried (column 12, lines 35-37). The recitation of "conductivity of between 3.5 to 6 millisiemens" would be an obvious experimental design choice. It is well known in the art to freeze and later thaw purified fractions at certain convenient points in the process of antibody purification. This is done to pool large amounts of purified antibody fractions before use or further processing or to store purified antibody fractions to be used at a later date. This is evidenced by Rhodes *(U.S. Patent No. 5,346, 687, published September 13, 1994)*, which teaches that frozen purified antibody can be frozen in a vial and maintained for indefinite period before use (claim 5).

Laursen et al do not teach the use of lactose.

Flaa et al teach stabilizing solutions for proteins and peptides (see the Title). Flaa et al teach that bulking agents such as lactose can be added to protein compositions, if the protein compositions are going to lyophilized or frozen (column 5, lines 63-67 and column 6, lines 1-3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the lactose as taught by Flaa et al to the IgG4 composition of Laursen et al because Laursen et al teach that saccharides are added to stabilize the IgG fraction and to adjust the osmolality of the IgG fraction (column 9, lines 17-26 and column 4, lines 20-23). It would be expected barring evidence to the contrary that the method of producing IgG4 as taught by Laursen et al and Flaa et al combined would produce purified amounts of IgG4 because Laursen et al teach that purified

amounts of IgG4 ranging from 0.6% to 1.5% are produced by the method (columns 17-18).

Status of Claims

5. No claims are allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
January 27, 2003

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